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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 095123 0008 Rev. 04

Manufacturer:

Hangzhou AllTest Biotech Co., Ltd.
550#, Yinhai Street
Hangzhou Economic and Technological Development Area
310018 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Products for determination of infection markers tumor markers and products for self testing**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V1 095123 0008 Rev. 04

Report no.: SH221064A02

Valid from: 2022-04-05
Valid until: 2025-05-26

Date, 2022-04-05

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Product Service

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Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 095123 0008 Rev. 04

Model(s):

Toxo IgG/IgM Rapid Test,
Rubella IgM Rapid Test,
CMV IgM Rapid Test,
ToRCH IgM Combo Rapid Test,
PSA Rapid Test,
PSA Qualitative Rapid Test,
Chlamydia Rapid Test,
Sperm Concentration Rapid Test,
SP-10 Male Fertility Rapid Test,
hCG Rapid Test,
Digital hCG Pregnancy Test
LH Rapid Test,
FSH Rapid Test,
Vaginal pH Rapid Test,
Ferritin Rapid Test,
TSH Rapid Test,
H.pylori Rapid Test,
Urinary Tract Infections Test,
FOB Rapid Test,
Vitamin D Rapid Test

Facility(ies):

Hangzhou AllTest Biotech Co., Ltd.
550#, Yinhai Street, Hangzhou Economic and Technological Development Area, 310018 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

.

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

EC Declaration of Conformity

Manufacturer:
Name： HANGZHOU ALLTEST BIOTECH CO., LTD.
Address：#550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou -310018, P.R. China

European Representative:
Name: MedNet EC-REP GmbH
Address: Borkstrasse 10, 48163 Muenster, Germany

Product (Group) Name: FOB (Fecal Occult Blood) Rapid Test (Feces)
Cat. No.: See attachment 1
Analyte: See attachment 1
Model: See attachment 1
Classification: Self-testing Device of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex IV
EDMA Code: 12 70 03 90 00

We, HANGZHOU ALLTEST BIOTECH CO., LTD., herewith declare that we are exclusively responsible for this declaration of conformity. We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:
DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied: EN ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN 13612:2002/AC: 2002, EN ISO 17511:2003, EN ISO 23640:2015, EN 13641:2002, EN 13532:2002, EN ISO 15223-1:2016
Notified body: TUV SUD Product service GmbH, Ridlerstrasse 65, 80339 Munich, Germany (0123)
(EC) Certificate(s): V1 095123 0008 Rev.04
Expire date of the Certificate: 2025-05-26
Place, Date of First issue of DOC: in Hangzhou on 2016-09-14
The Date of Issue of DOC on 2022-04-0

Signature: _____
Name: GAO FEI (Position: General Manager)

Hangzhou AllTest Biotech Co.,Ltd.
#550, Yinhai Street,
Hangzhou Economic & Technological Development Area,
Hangzhou -310018, P.R. China

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邮 箱：info@alltests.com.cn
网 址：www.alltests.com.cn

Attachment 1

Catalog NO.	Product Name	Analyte	Model
TFO-601H	FOB Rapid Test Dipstick (Feces)	Fecal Occult Blood in human Feces	Dipstick
TFO-602H	FOB Rapid Test Cassette (Feces)	Fecal Occult Blood in human Feces	Cassette

Hangzhou AllTest Biotech Co.,Ltd.
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Hangzhou Economic & Technological
Development Area,
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Registration File of

FOB Rapid Test (Feces)

TFO-601H/602H

Registration No.: SRG0109

Version: 03

Table of Contents

1 BACKGROUND

Many diseases can cause hidden blood in the feces. This is also known as Fecal Occult Blood (FOB), Human Occult Blood, or Human Hemoglobin. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood. Traditional guaiac-based methods lack sensitivity and specificity, and also have diet restrictions prior to testing.[1,2]

The FOB Rapid Test (Feces) is a rapid test to qualitatively detect low levels of Fecal Occult Blood. The test uses a double antibody sandwich assay to selectively detect Fecal Occult Blood at 50ng/ml or higher, or 6µg/g feces. In addition, unlike guaiac assays, the accuracy of the test is not affected by the diet of the patients.

1.1 Test Principle

The FOB Rapid Test (Feces) is a qualitative, lateral flow immunoassay for the detection of Human Occult Blood in feces. The membrane is precoated with anti-hemoglobin antibody on the test line region of the test. During testing, the specimen reacts with the particle coated with anti-hemoglobin antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hemoglobin antibody on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

1.2 Illustrations

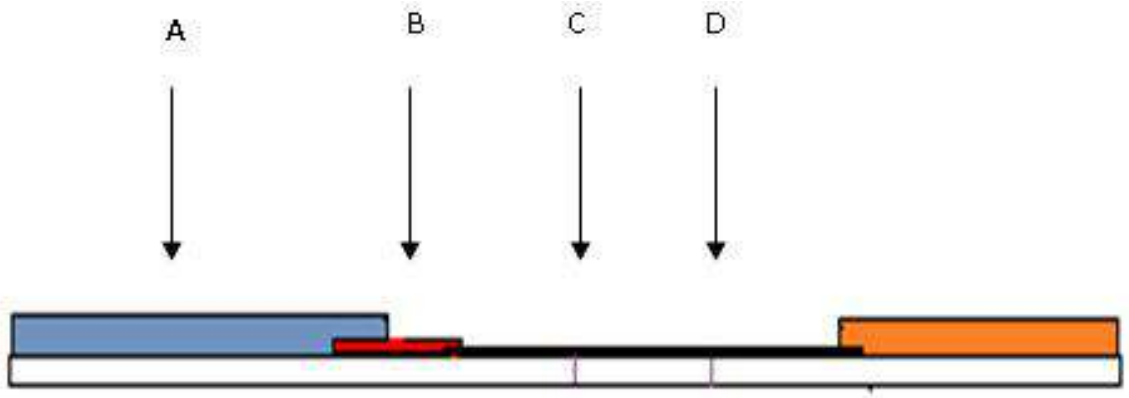

Figure 1: Test Principle

As shown in illustration above, the specimen (A) migrates via capillary action along the membrane to react with the colored conjugate (B). Human hemoglobin present in the specimen binds to the conjugate, forming a colored antibody-antigen complex. The mouse anti-human hemoglobin immobilized in the test zone of the membrane captures the test region (C). The formation of a visible colored line in the test region indicates a positive result (C). The absence of

a colored line in the test zones suggests a negative result. In the control zone of the membrane, immobilized reagents capture colored conjugate regardless of test specimen composition. The resulting visible colored band (D) confirms control line.

1.3 Precautions

- In vitro diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- Do not eat, drink and smoke in the area where the specimen or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautious against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

1.4 Storage

Store the test at 2-30°C. Freezing must be avoided.

1.5 Stability

The FOB Rapid Test Cassette (Feces) is stable for 24 months from the date of production when stored properly in unopened aluminum foil pouches with desiccant.

1.6 Specimen Collection and Preparation

- Specimens should not be collected during or within three days of a menstrual period, or if the patient suffers from bleeding hemorrhoids or blood in the urine.
- Alcohol, aspirin and other medications taken in excess may cause gastrointestinal irritation resulting in occult bleeding. Such substances should be discontinued at least 48 hours prior to testing.
- No dietary restrictions are necessary before using the FOB Rapid Test Cassette.

1.7 Directions for Use

TFO-601H

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. To collect fecal specimens:
   The stool specimen should be collected in the stool catcher. Please use the stool catcher in all sorts of toilets to avoid contamination of the specimen with any kind of chemicals, so that no adulteration of the specimen occur.
2. To process fecal specimens:
   Unscrew the cap of the specimen collection tube， then randomly stab the specimen collection applicator into the fecal specimen in at least **3 different sites**. Do not scoop the fecal specimen.

Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer.

3. Bring the pouch to room temperature before opening it. Remove the test dipstick from the foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
4. Fix the reaction tube, hold the specimen collection tube upright and break off the tip of the specimen collection tube. Invert the specimen collection tube and transfer **8-10 full drops of the extracted specimen (approx. 500µL)** to the reaction tube, then with arrows pointing toward the exaction buffer, immerse the dipstick and start the timer. Do not immerse the dipstick past the maximum line. See illustration below.
5. Read results at **5 minutes.** Do not read results after 10 minutes.

TFO-602H

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

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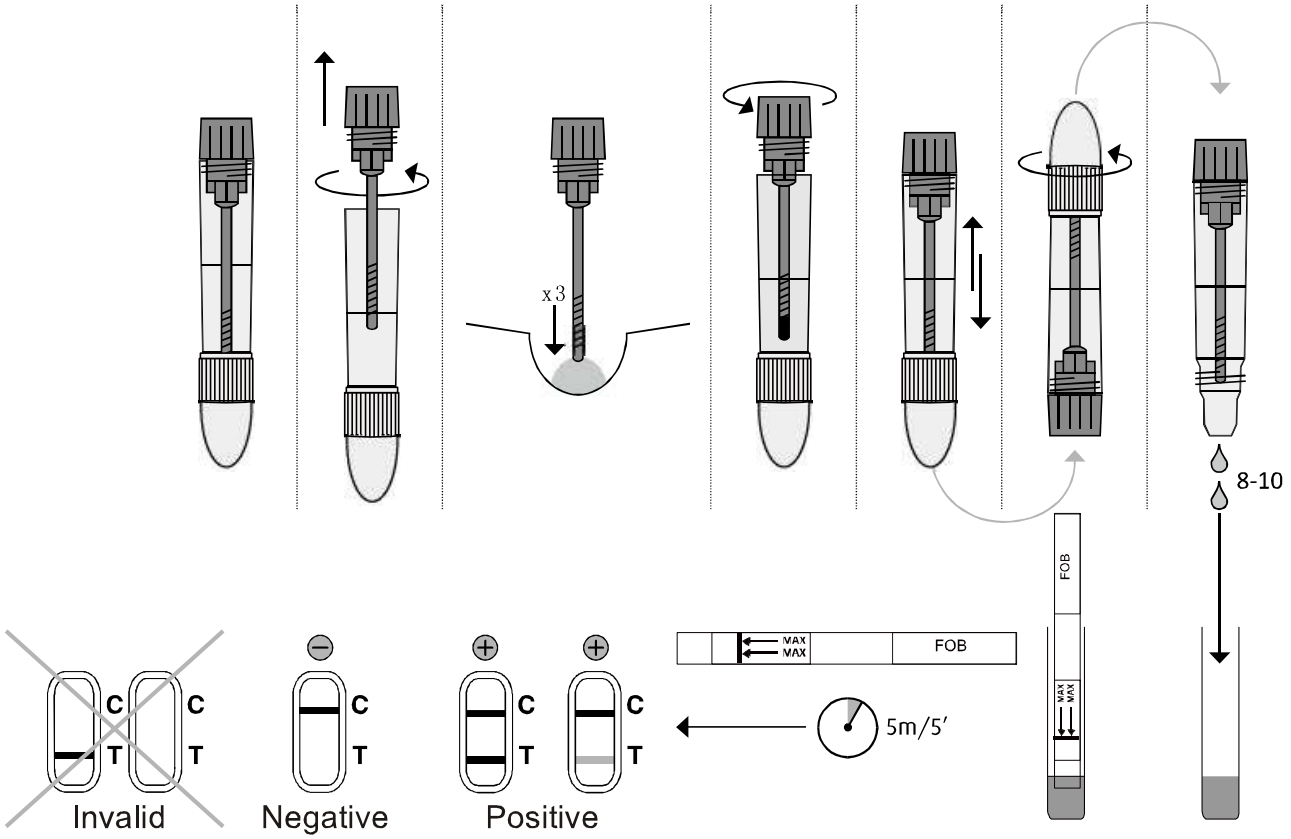
2. To process fecal specimens:
   Unscrew the cap of the specimen collection tube， then randomly stab the specimen collection applicator into the fecal specimen in at least **3 different sites**. Do not scoop the fecal specimen.
   Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer.
3. Bring the pouch to room temperature before opening it. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
4. Hold the specimen collection tube upright and open the cap onto the specimen collection tube. Invert the specimen collection tube and transfer **2 full drops of the extracted specimen (approximately 80µL)** to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
5. Read results at **5 minutes**. Do not read results after 10 minutes.


x3
8-10
FOB
MAX
MAX
C
T
Invalid
Negative
Positive
5m/5′

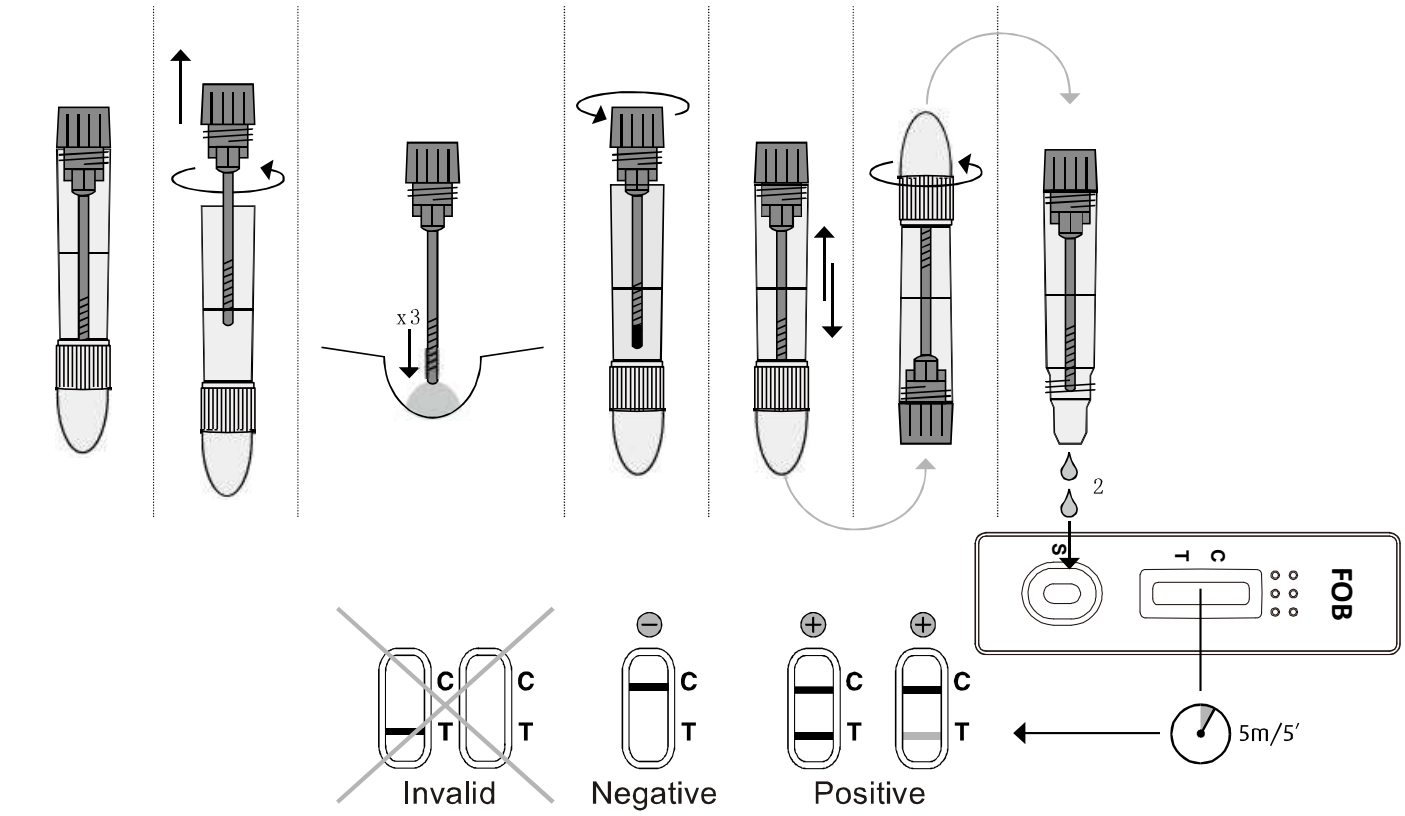

x3
2
S
C
T
FOB
C
T
Invalid
Negative
Positive
5m/5′

Figure 2: Interpretation of Results

1.8 Interpretation of Result

POSITIVE:* Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).
***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of Fecal Occult Blood present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.
NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

1.9 Quality Control

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal valid procedural control. It confirms sufficient specimen volume and correct procedural technique.
Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

1.10 Limitation

1. The FOB Rapid Test Cassette (Feces) is for in vitro diagnostic use only.
2. The FOB Rapid Test Cassette (Feces) will only indicate the presence of Fecal Occult Blood, the presence of blood in feces does not necessarily indicate colorectal bleeding.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. Other clinically available tests are required if questionable results are obtained.

1.11 Description of Test Methods

1.11.1 General remarks

The Quality Control department performs testing according to written procedures. Testing equipment is checked prior to use and calibrated at scheduled frequencies.

1.11.2 Receiving inspection and control of raw materials

A sample batch of each raw material (chemicals, packaging and labeling) is inspected/tested (where applicable) for suitability and functionality. Primary packaging is inspected for correct

dimensions, cleanliness and suitability. Only QC "APPROVED" raw material is employed for production.

1.12 Composition of Product

A) Mouse anti-Hemoglobin (Capture)
B) Mouse anti-Hemoglobin (Detection)
C) Mouse IgG
D) Goat anti-mouse IgG
E) Adhesive plastic backing
F) Label pad
G) Absorbant pad
H) Sample pad
I) NC membrane
J) Desiccant (in pouch)
K) Pouch
L) Sample collection tube with reaction solution
M) Extraction Tube

1.13 Manufacturing Procedure

- Coat the gold conjugated mouse anti-hemoglobin and mouse IgG on the label pad.
- Use the sprayer to dispense goat anti-mouse IgG and mouse anti-hemoglobin onto the membrane.
- Assemble the membrane, label pad, absorbent pad, sample pad and strip label on the plastic backing.
- Use the cutter to cut the plastic backing into strips of selected size.
- Test the strips according to the QC procedure and release the finished product.

1.14 Expected Values

1. How does the test dipstick work?

FOB Rapid Test Dipstick detects human hemoglobin in your feces specimen that your body produces during. The rate of disease progression is not indicated by this test.

2. How much occult blood could be detected out in the feces specimen?

The FOB Rapid Test can detect fecal occult blood at the level of 50ng/ml or 6ug/g feces.

3. How accurate is the test?

A clinical evaluation was conducted comparing the results obtained using the FOB Rapid Test to another commercially available FOB test. The consumer clinical trial included 464 feces specimens: The FOB Test identified 63 positive and 397 negative results. The results demonstrated 99.1% overall accuracy of the FOB Rapid Test when compared to the other FOB rapid test.

4. What's the storage condition of the feces specimen

Generally speaking, the fresh specimen should be used within 1 day at room temperature, in order to get correct results.

5. What should I do if the result shows occult blood in the fecal?

You should see a doctor and seek medical opinions.

2 PERFORMANCE CHARACTERISTICS

2.1 Sample Correlation

1.1.1. Method

The FOB Rapid Test (Feces) has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. Other rapid test served as the reference method for the FOB Rapid Test (Feces). The specimen was considered positive if other rapid test results were positive. The specimen was also considered negative if the other rapid test results were negative. The lot of AllTest FOB Rapid Test Dipstick is FOB15090001-T, lot of FOB Rapid Test Cassette is FOB15090004-T.

Table: TFO-601H Result

Method		**Other Rapid Test Result**		**Total**
FOB Rapid Test Dipstick	Results	Positive	Negative	
	Positive	63	3	66
	Negative	1	397	398
Total Results		64	400	464

Sensitivity Agreement: 98.4% (95%CI*: 91.6%-100%) * Confidence Intervals
Specificity Agreement: 99.3% (95%CI*: 97.8%-99.8%)
Overall Accuracy: 99.1% (95%CI*: 97.8%-99.8%)

Table: TFO-602H Result

Method		**Other Rapid Test Result**		**Total**
FOB Rapid Test Cassette	Results	Positive	Negative	
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Specificity Agreement: 99.3% (95%CI*: 97.8%-99.8%)
Overall Accuracy: 99.1% (95%CI*: 97.8%-99.8%)

1.1.2. Conclusion

Clinical test has been conducted on altogether 464 specimens.Results above indicated that sensitivity of FOB self-testing rapid test was 98.4%, specificity could reach to 99.3%, and the total accuracy was 99.1% according to the other FOB rapid test.

2.2 Analytical Sensitivity

2.2.1. Method

ANALYTICAL SENSITIVITY WITH HUMAN HEMOGLOBIN SPIKED IN EXTRACTION BUFFER

Human hemoglobin was spiked into extraction buffer at the concentration of 0ng/ml (negative control) 37.5ng hHb/ml, 50ng hHb/ml, and 62.5ng hHb/ml, among which 50ng hHb/ml is our designed cut-off value.

For FOB Test Cassette:

Add 2 drops (approx. 90ul) of hemoglobin solution to FOB cassette in 10 replicates for each concentration. Twist the chamber on to start the sample testing. Results were rated as either positive or negative at the reading time. Results are showed in table below.

For FOB Test Dipstick:

Add 8-10 drops (approx. 500ul) of hemoglobin solution to the extraction tube in 10 replicates for each concentration. With arrow point down, place the Dipstick into extraction tube (Note: level of solution can't pass the "MAX" line). Results were rated as either positive or negative at the reading time. Results are showed in table below.

Table: Analytical Sensitivity with Aqueous Hemoglobin

Test terms	Test number	FOB Dipstick Result					
		FOB15090001-T		FOB15090002-T		FOB15090003-T	
		5 minutes	10 minutes	5 minutes	10 minutes	5 minutes	10 minutes
37.5ng hHb/ml solution	1	-*	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
	6	-	-	-	-	-	-
	7	-	-	-	-	-	-
	8	-	-	-	-	-	-
	9	-	-	-	-	-	-
	10	-	-	-	-	-	-
50ng hHb/ml solution	1	+**	+	+	+	+	+
	2	+	+	+	+	+	+
	3	+	+	+	+	+	+
	4	+	+	+	+	+	+
	5	+	+	+	+	+	+
	6	+	+	+	+	+	+
	7	+	+	+	+	+	+
	8	+	+	+	+	+	+
	9	+	+	+	+	+	+
	10	+	+	+	+	+	+

62.5ng hHb/ml solution	1	+	+	+	+	+	+
	2	+	+	+	+	+	+
	3	+	+	+	+	+	+
	4	+	+	+	+	+	+
	5	+	+	+	+	+	+
	6	+	+	+	+	+	+
	7	+	+	+	+	+	+
	8	+	+	+	+	+	+
	9	+	+	+	+	+	+
	10	+	+	+	+	+	+
Test Terms	Test number	FOB Cassette Result					
		FOB15090004-T		FOB15090005-T		FOB15090006-T	
		5 minutes	10 minutes	5 minutes	10 minutes	5 minutes	10 minutes
37.5ng hHb/ml solution	1	-	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
	6	-	-	-	-	-	-
	7	-	-	-	-	-	-
	8	-	-	-	-	-	-
	9	-	-	-	-	-	-
	10	-	-	-	-	-	-
50ng hHb/ml solution	1	+	+	+	+	+	+
	2	+	+	+	+	+	+
	3	+	+	+	+	+	+
	4	+	+	+	+	+	+
	5	+	+	+	+	+	+
	6	+	+	+	+	+	+
	7	+	+	+	+	+	+
	8	+	+	+	+	+	+
	9	+	+	+	+	+	+
	10	+	+	+	+	+	+
62.5ng hHb/ml solution	1	+	+	+	+	+	+
	2	+	+	+	+	+	+
	3	+	+	+	+	+	+
	4	+	+	+	+	+	+
	5	+	+	+	+	+	+
	6	+	+	+	+	+	+
	7	+	+	+	+	+	+
	8	+	+	+	+	+	+

	9	+	+	+	+	+	+
	10	+	+	+	+	+	+

Note: “*” mean negative result; “**” mean positive result

2.2.2. Conclusion: The FOB Rapid Test Cassette (Feces) can detect levels of human hemoglobin as low as 50ng/ml.

2.2.3. Method

ANALYTICAL SENSITIVITY WITH HUMAN HEMOGLOBIN SPIKED IN FECES

Collect 10 pre-assumed negative feces. Prepare human hemoglobin stock solution by spiked human hemoglobin to extraction buffer to 2mg/ml concentration. Spike the human hemoglobin stock solution to collect negative feces to the concentration of 0ug/g feces, 4.5ug/g feces, 6ug/g and 7.5ug/g feces. Results were rated as either positive or negative at the call time. Results are shown in table below:

Table: Analytical Sensitivity with Human Hemoglobin spiked in feces

Test terms	Test number	Result					
		FOB15090001-T		FOB15090002-T		FOB15090003-T	
		5 minutes	10 minutes	5 minutes	10 minutes	5 minutes	10 minutes
4.5ug/g feces	1	-*	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
	6	-	-	-	-	-	-
	7	-	-	-	-	-	-
	8	-	-	-	-	-	-
	9	-	-	-	-	-	-
	10	-	-	-	-	-	-
6ug/g feces	1	+**	+	+	+	+	+
	2	+	+	+	+	+	+
	3	+	+	+	+	+	+
	4	+	+	+	+	+	+
	5	+	+	+	+	+	+
	6	+	+	+	+	+	+
	7	+	+	+	+	+	+
	8	+	+	+	+	+	+
	9	+	+	+	+	+	+
	10	+	+	+	+	+	+
7.5ug/g feces	1	+	+	+	+	+	+
	2	+	+	+	+	+	+
	3	+	+	+	+	+	+
	4	+	+	+	+	+	+
	5	+	+	+	+	+	+
	6	+	+	+	+	+	+
	7	+	+	+	+	+	+

	8	+	+	+	+	+	+
	9	+	+	+	+	+	+
	10	+	+	+	+	+	+
Test Terms	Test number	Result					
		FOB15090004-T		FOB15090005-T		FOB15090006-T	
		5 minutes	10 minutes	5 minutes	10 minutes	5 minutes	10 minutes
4.5ug/g feces	1	-	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
	6	-	-	-	-	-	-
	7	-	-	-	-	-	-
	8	-	-	-	-	-	-
	9	-	-	-	-	-	-
	10	-	-	-	-	-	-
6ug/g feces	1	+	+	+	+	+	+
	2	+	+	+	+	+	+
	3	+	+	+	+	+	+
	4	+	+	+	+	+	+
	5	+	+	+	+	+	+
	6	+	+	+	+	+	+
	7	+	+	+	+	+	+
	8	+	+	+	+	+	+
	9	+	+	+	+	+	+
	10	+	+	+	+	+	+
7.5ug/g feces	1	+	+	+	+	+	+
	2	+	+	+	+	+	+
	3	+	+	+	+	+	+
	4	+	+	+	+	+	+
	5	+	+	+	+	+	+
	6	+	+	+	+	+	+
	7	+	+	+	+	+	+
	8	+	+	+	+	+	+
	9	+	+	+	+	+	+
	10	+	+	+	+	+	+

Note: “*” mean negative result; “**” mean positive result

Conclusion: The FOB Rapid Test (Feces) can detect levels of Fecal Occult Blood as low as 50ng/ml or 6ug/g feces.

2.3 Interfering Substances

2.3.1. Method

Analytes were spiked into diluting buffer and middle positive sample (100ng/ml hemoglobin in diluting buffer) at the concentrations listed. The specimens were tested in triplicate with 3 lots of test cassettes and dipsticks. Visual interpretations were made at 5 and 10 minutes after specimen application. The results are presented in table below.

Table: Interfering Substance

FOB Rapid Test Dipstick

Analytes	Concentration	Sample								
		Negative								
		FOB15090001-T			FOB15090002-T			FOB15090003-T		
Ascoribic acid	20mg/dl	-*	-	-	-	-	-	-	-	-
Oxalic acid	60mg/dl	-	-	-	-	-	-	-	-	-
Bilirubin	100mg/dl	-	-	-	-	-	-	-	-	-
Uric acid	60mg/dl	-	-	-	-	-	-	-	-	-
Aspirin	20mg/dl	-	-	-	-	-	-	-	-	-
Urea	2000mg/dl	-	-	-	-	-	-	-	-	-
Glucose	2000mg/dl	-	-	-	-	-	-	-	-	-
Caffeine	40mg/dl	-	-	-	-	-	-	-	-	-
Albumin	2000mg/dl	-	-	-	-	-	-	-	-	-
Analytes	**Concentration**	**Sample**								
		100ng/ml hemoglobin								
		FOB15090001-T			**FOB15090002-T**			**FOB15090003-T**		
Ascoribic acid	20mg/dl	+**	+	+	+	+	+	+	+	+
Oxalic acid	60mg/dl	+	+	+	+	+	+	+	+	+
Bilirubin	100mg/dl	+	+	+	+	+	+	+	+	+
Uric acid	60mg/dl	+	+	+	+	+	+	+	+	+
Aspirin	20mg/dl	+	+	+	+	+	+	+	+	+
Urea	2000mg/dl	+	+	+	+	+	+	+	+	+
Glucose	2000mg/dl	+	+	+	+	+	+	+	+	+
Caffeine	40mg/dl	+	+	+	+	+	+	+	+	+
Albumin	2000mg/dl	+	+	+	+	+	+	+	+	+

Note: "*" mean negative result, "**" mean positive result

FOB Rapid Test Cassette

Analytes	Concentration	Sample								
		Negative								
		FOB15090004-T			FOB15090005-T			FOB15090006-T		
Ascoribic acid	20mg/dl	-*	-	-	-	-	-	-	-	-
Oxalic acid	60mg/dl	-	-	-	-	-	-	-	-	-
Bilirubin	100mg/dl	-	-	-	-	-	-	-	-	-
Uric acid	60mg/dl	-	-	-	-	-	-	-	-	-

Aspirin	20mg/dl	-	-	-	-	-	-	-	-	-
Urea	2000mg/dl	-	-	-	-	-	-	-	-	-
Glucose	2000mg/dl	-	-	-	-	-	-	-	-	-
Caffeine	40mg/dl	-	-	-	-	-	-	-	-	-
Albumin	2000mg/dl	-	-	-	-	-	-	-	-	-
Analytes	**Concentration**	**Sample**								
		100ng/ml hemoglobin								
		FOB15090004-T			**FOB15090005-T**			**FOB15090006-T**		
Ascoribic acid	20mg/dl	+**	+	+	+	+	+	+	+	+
Oxalic acid	60mg/dl	+	+	+	+	+	+	+	+	+
Bilirubin	100mg/dl	+	+	+	+	+	+	+	+	+
Uric acid	60mg/dl	+	+	+	+	+	+	+	+	+
Aspirin	20mg/dl	+	+	+	+	+	+	+	+	+
Urea	2000mg/dl	+	+	+	+	+	+	+	+	+
Glucose	2000mg/dl	+	+	+	+	+	+	+	+	+
Caffeine	40mg/dl	+	+	+	+	+	+	+	+	+
Albumin	2000mg/dl	+	+	+	+	+	+	+	+	+

Note: "*" mean negative result, "**" mean positive result

2.3.2. Conclusion

No substances showed any interference with the test. There were no differences observed between the results at 5 minutes and the results at 10 minutes.

2.4 Between Day Reproducibility

2.4.1. Method

Negative, 50ng/ml hemoglobin, 100ng/ml hemoglobin and 10ug/ml hemoglobin samples were run individually on ten separate days using the same lot of FOB rapid test dipstick and FOB Rapid Test Cassette. Results were rated visually as positive or negative at 5 minutes and 10 minutes after specimen application. Results are presented in table below.

Table: Between Day Results

FOB Rapid Test Dipstick

		Lot#: FOB15090001-T									
Day		1	2	3	4	5	6	7	8	9	10
Negative	5 minutes	15-*	15-	15-	15-	15-	15-	15-	15-	15-	15-
	10 minutes	15-	15-	15-	15-	15-	15-	15-	15-	15-	15-
50ng/ml	5 minutes	15+**	15+	15+	15+	15+	15+	15+	15+	15+	15+
	10 minutes	15+	15+	15+	15+	15+	15+	15+	15+	15+	15+
100ng/ml	5 minutes	15+	15+	15+	15+	15+	15+	15+	15+	15+	15+
	10 minutes	15+	15+	15+	15+	15+	15+	15+	15+	15+	15+
10ug/ml	5 minutes	15+	15+	15+	15+	15+	15+	15+	15+	15+	15+
	10 minutes	15+	15+	15+	15+	15+	15+	15+	15+	15+	15+

Note: “*” mean all 15 results were negative, “**” mean all 15 results were positive

FOB Rapid Test Cassette

		Lot#: FOB15090004-T									
Day		1	2	3	4	5	6	7	8	9	10
Negative	5 minutes	15-*	15-	15-	15-	15-	15-	15-	15-	15-	15-
	10 minutes	15-	15-	15-	15-	15-	15-	15-	15-	15-	15-
50ng/ml	5 minutes	15+**	15+	15+	15+	15+	15+	15+	15+	15+	15+
	10 minutes	15+	15+	15+	15+	15+	15+	15+	15+	15+	15+
100ng/ml	5 minutes	15+	15+	15+	15+	15+	15+	15+	15+	15+	15+
	10 minutes	15+	15+	15+	15+	15+	15+	15+	15+	15+	15+
10ug/ml	5 minutes	15+	15+	15+	15+	15+	15+	15+	15+	15+	15+
	10 minutes	15+	15+	15+	15+	15+	15+	15+	15+	15+	15+

Note: “*” mean all 15 results were negative, “**” mean all 15 results were positive

2.4.2. Conclusion

Conclusion: Test results were consistent over ten day’s period

2.5 Between Lot Reproducibility

2.5.1. Method

Negative (extraction buffer), 50ng/ml hemoglobin sample, 100ng/ml hemoglobin positive sample and 10ug/ml hemoglobin positive sample were run in replicates of ten in three separate lots of product. Results were rated as positive or negative at 5 and 10 minutes after specimen application. The results are present in table below.

Table: Between Lot Result

FOB Rapid Test Dipstick

Sample	No.	FOB15090001-T		FOB15090002-T		FOB15090003-T	
		5 MIN	10 MIN	5 MIN	10 MIN	5 MIN	10 MIN
Negative	1	-*	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
	6	-	-	-	-	-	-
	7	-	-	-	-	-	-
	8	-	-	-	-	-	-
	9	-	-	-	-	-	-
	10	-	-	-	-	-	-
	11	-	-	-	-	-	-
	12	-	-	-	-	-	-
	13	-	-	-	-	-	-
	14	-	-	-	-	-	-
	15	-	-	-	-	-	-
50ng/ml	1	+**	+	+	+	+	+
	2	+	+	+	+	+	+
	3	+	+	+	+	+	+
	4	+	+	+	+	+	+
	5	+	+	+	+	+	+
	6	+	+	+	+	+	+
	7	+	+	+	+	+	+
	8	+	+	+	+	+	+
	9	+	+	+	+	+	+
	10	+	+	+	+	+	+
	11	+	+	+	+	+	+
	12	+	+	+	+	+	+
	13	+	+	+	+	+	+
	14	+	+	+	+	+	+
	15	+	+	+	+	+	+
100ng/ml	1	+	+	+	+	+	+

	2	+	+	+	+	+	+
	3	+	+	+	+	+	+
	4	+	+	+	+	+	+
	5	+	+	+	+	+	+
	6	+	+	+	+	+	+
	7	+	+	+	+	+	+
	8	+	+	+	+	+	+
	9	+	+	+	+	+	+
	10	+	+	+	+	+	+
	11	+	+	+	+	+	+
	12	+	+	+	+	+	+
	13	+	+	+	+	+	+
	14	+	+	+	+	+	+
	15	+	+	+	+	+	+
10ug/ml	1	+	+	+	+	+	+
	2	+	+	+	+	+	+
	3	+	+	+	+	+	+
	4	+	+	+	+	+	+
	5	+	+	+	+	+	+
	6	+	+	+	+	+	+
	7	+	+	+	+	+	+
	8	+	+	+	+	+	+
	9	+	+	+	+	+	+
	10	+	+	+	+	+	+
	11	+	+	+	+	+	+
	12	+	+	+	+	+	+
	13	+	+	+	+	+	+
	14	+	+	+	+	+	+
	15	+	+	+	+	+	+

Note: “*” mean negative result, “**” mean positive result

FOB Rapid Test Cassette

Sample	No.	FOB15090004-T		FOB15090005-T		FOB15090006-T	
		5 MIN	10 MIN	5 MIN	10 MIN	5 MIN	10 MIN
Negative	1	-*	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
	6	-	-	-	-	-	-
	7	-	-	-	-	-	-
	8	-	-	-	-	-	-
	9	-	-	-	-	-	-

	10	-	-	-	-	-	-
	11	-	-	-	-	-	-
	12	-	-	-	-	-	-
	13	-	-	-	-	-	-
	14	-	-	-	-	-	-
	15	-	-	-	-	-	-
50ng/ml	1	+**	+	+	+	+	+
	2	+	+	+	+	+	+
	3	+	+	+	+	+	+
	4	+	+	+	+	+	+
	5	+	+	+	+	+	+
	6	+	+	+	+	+	+
	7	+	+	+	+	+	+
	8	+	+	+	+	+	+
	9	+	+	+	+	+	+
	10	+	+	+	+	+	+
	11	+	+	+	+	+	+
	12	+	+	+	+	+	+
	13	+	+	+	+	+	+
	14	+	+	+	+	+	+
	15	+	+	+	+	+	+
100ng/ml	1	+	+	+	+	+	+
	2	+	+	+	+	+	+
	3	+	+	+	+	+	+
	4	+	+	+	+	+	+
	5	+	+	+	+	+	+
	6	+	+	+	+	+	+
	7	+	+	+	+	+	+
	8	+	+	+	+	+	+
	9	+	+	+	+	+	+
	10	+	+	+	+	+	+
	11	+	+	+	+	+	+
	12	+	+	+	+	+	+
	13	+	+	+	+	+	+
	14	+	+	+	+	+	+
	15	+	+	+	+	+	+
10ug/ml	1	+	+	+	+	+	+
	2	+	+	+	+	+	+
	3	+	+	+	+	+	+
	4	+	+	+	+	+	+
	5	+	+	+	+	+	+
	6	+	+	+	+	+	+

	7	+	+	+	+	+	+
	8	+	+	+	+	+	+
	9	+	+	+	+	+	+
	10	+	+	+	+	+	+
	11	+	+	+	+	+	+
	12	+	+	+	+	+	+
	13	+	+	+	+	+	+
	14	+	+	+	+	+	+
	15	+	+	+	+	+	+

Note: “*” mean negative result, “**” mean positive result

2.5.2. Conclusion

Test results were consistent between the 3 lots of FOB Rapid Test Dipstick and 3 lots of FOB Rapid Test Cassette.

2.6 Cross Reactivity Study

2.6.1. Method

Animal's hemoglobin, such as pig's, bovine's, chicken's goat's, rabbit's, horse's, turkey's hemoglobin and human hemoglobin were spiked into the diluting buffer respectively at 1mg/ml and tested with the FOB Rapid Test Cassette/Dipstick (Feces). Visual interpretation were made at 5 minutes, do not interpret the results after 10 minutes. The results are presented in Table below:

Table: Cross Reactivity Study

Treatment (1mg/ml)	**Results of Test Dipstick**					
	FOB15090001-T		FOB15090002-T		FOB15090003-T	
	5 minutes	10 minutes	5 minutes	10 minutes	5 minutes	10 minutes
Bovine hemoglobin	-*	-	-	-	-	-
Chicken hemoglobin	-	-	-	-	-	-
Pork hemoglobin	-	-	-	-	-	-
Goat hemoglobin	-	-	-	-	-	-
Horse hemoglobin	-	-	-	-	-	-
Rabbit hemoglobin	-	-	-	-	-	-
Turkey hemoglobin	-	-	-	-	-	-
Human Hemoglobin	+**	+	+	+	+	+
Treatment (1mg/ml)	**Results of Test Cassette**					
	FOB15090004-T		FOB15090005-T		FOB15090006-T	
	5 minutes	10 minutes	5 minutes	10 minutes	5 minutes	10 minutes
Bovine hemoglobin	-	-	-	-	-	-
Chicken hemoglobin	-	-	-	-	-	-
Pork hemoglobin	-	-	-	-	-	-
Goat hemoglobin	-	-	-	-	-	-
Horse hemoglobin	-	-	-	-	-	-
Rabbit hemoglobin	-	-	-	-	-	-
Turkey hemoglobin	-	-	-	-	-	-
Human Hemoglobin	+	+	+	+	+	+

Note: "*" mean negative result, "**"mean positive result

2.6.2. Conclusion

The FOB Rapid Test Cassette/Dipstick (Feces) is specific to human hemoglobin. Bovine hemoglobin, Chicken hemoglobin, Pork hemoglobin, Goat hemoglobin, Horse hemoglobin, Horse hemoglobin, Rabbit hemoglobin and Turkey hemoglobin show no cross-reactivity at 5 minutes when tested at concentration of 1mg/ml.

2.7 Accelerated Stability

2.7.1. Method

Accelerated Stability of the FOB Rapid Test was evaluated using samples from 3 different batches. These were placed in an incubator with the temperature calibrated at 45℃ and 55℃. Relative humidity (RH) calibrated at about 60%. A series of stability tests were performed at 0, 7, 14, 21, 28, 35, 42, 56, 77, 84 days for 45℃. About 55℃, some performance study would be tested at 0, 7, 14, 21, 28, 35, 42 days according to Arrhenius Plot. See Table in below. Test cassettes were assayed using negative, 50ng/ml, 100ng/ml and 10ug/ml. Testing at each specific time interval consisted of 3 replicates for each specimen. The tests were performed according to the package insert. Results are presented in Table below.

Arrhenius Formula:

In K=-Ea/RT + In A

"K" mean Rate constant

"A" mean Arrhenius constant

"Ea" mean Activation energy

"R" mean Gas constant

"T" mean Temperature in Kelvin

Table: Time line for Accelerate Stability Study

Day / Temp.	0day	7days	14 days	21 days	28 days	35 days	42 days	56 days	77 days	84 days
45℃	√	√	√	√	√	√	√	√	√	√
55℃	√	√	√	√	√	√	√	×	×	×

Table: 45℃Accelerated Stability Summary

Day	Specimen	FOB Rapid Test Dipstick (TFO-601H)								
		FOB15090001-T			FOB15090002-T			FOB15090003-T		
0	Negative	-*	-	-	-	-	-	-	-	-
	50ng/ml Hb	+**	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+

	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
56	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
77	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
84	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+

Day	**Specimen**	**FOB Rapid Test Cassette (TFO-602H)**								
		TFO14040004-T			TFO14040005-T			TFO14040006-T		
0	Negative	-*	-	-	-	-	-	-	-	-
	50ng/ml Hb	+**	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+

	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
56	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
77	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
84	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+

Note: "*" mean negative result, "" mean positive result**

Table: 55℃ Accelerated Stability Summary

Day	Specimen	FOB Rapid Test Dipstick (TFO-601H)								
		FOB15090001-T			FOB15090002-T			FOB15090003-T		
0	Negative	-*	-	-	-	-	-	-	-	-
	50ng/ml Hb	+**	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+

	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
Day	**Specimen**	**FOB Rapid Test Cassette (TFO-602H)**								
		TFO14040004-T			TFO14040005-T			TFO14040006-T		
0	Negative	-*	-	-	-	-	-	-	-	-
	50ng/ml Hb	+**	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+

	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-
	50ng/ml Hb	+	+	+	+	+	+	+	+	+
	100ng/ml Hb	+	+	+	+	+	+	+	+	+
	10ug/ml Hb	+	+	+	+	+	+	+	+	+

Note: "*" mean negative result, "" mean positive result**

2.7.2. Conclusion

The FOB Rapid Test was stable at 45℃ for 84 days and at 55℃ for 42 days. These data were plotted on an Arrhenius Plot and the shelf life of this product was determined to be at least 27 months from the data of manufacture

3 BIBLIOGRAPHY

1. Simon JB. Occult Blood Screening for Colorectal Carcinoma: A Critical Review, Gastroenterology, 1985; 88: 820.
2. Blebea J, Mcpherson RA. False-Positive Guaiac Testing With Iodine, Arch Pathol Lab Med, 1985;109:437-40.

Document History Summary

Version No.	Date	Description	Remark
01	2015.11.30	/	N/A
02	2016.06.15	1. Subjoin more information about the product into “ Directions for Use” from page 4 to page 6.	N/A
03	2019.04.26	1. update the “Precaution” same as package inset according to requirement from TUV. 2. The storage condition and shelf life will be change in the “Expected Values” according to requirement from TUV because of self-testing.	N/A

Certificate of Analysis

Product Name: FOB Rapid Test Cassette (Feces)

Catalog No.: TFO-602H

Batch No.: FOB25020039

Quantity:1000PCS

Expiry Date:2027-01

Date of Sampling:2025-03-04

Date of Analysis:2025-03-04

Other information:

Buffer Lot: 25025320,Exp:2027-01

QC Item		QC Criterion	QC Result	Conclusion
Physical	Appearance	Good	Good	Pass
Functional Performance	100ng/ml	Positive	100% Positive	Pass
	50ng/ml	Positive	100% Positive	Pass
	Negative Sample	Negative	100% Negative	Pass

Others	/

Final QC Conclusion：	This batch of product met the QC Criteria.

QC supervisor: Freeman.zheng

Date: 2025.03.04

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